UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,922	03/15/2007	Barry Slobedman	SPRUS61.001APC	8791
20995 7590 01/04/2011 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER	
			STOICA, ELLY GERALD	
			ART UNIT	PAPER NUMBER
			1647	
			NOTIFICATION DATE	DELIVERY MODE
			01/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com efiling@kmob.com eOAPilot@kmob.com

Office Action Summary 10/580,922 SLOBEDMAN ET AL.				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
 WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 				
Status .				
1) Responsive to communication(s) filed on 11/08/2010.				
2a) ☑ This action is FINAL . 2b) ☐ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4) \boxtimes Claim(s) <u>1,6-8,24,28,30-32,40-44,52 and 58-62</u> is/are pending in the application.				
4a) Of the above claim(s) <u>40-44</u> is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
6) Claim(s) <u>1,6-8,24,28,30-32,52 and 58-62</u> is/are rejected.				
7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or election requirement.				
Application Papers				
9)☐ The specification is objected to by the Examiner.				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage				
application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)				
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date				
Notice of Braitsperson's Faterit Brawing Neview (170-545) Notice of Informal Patent Application Notice of Informal Patent Application				
Pat er No(s)/Mail Date 6) Other:				

Art Unit: 1647

DETAILED ACTION

Response to Amendment

1. In the reply filed on 11/08/2009, Applicant amended claims 1, 6, 8, 28, 30-32, 40, 52, 58 and added the new claims 59-62. Claims 1, 6-8, 24, 28, 30-32, 40-44, 52 and 58-62 are presently pending. In view of the amendment and the explanations accompanying it, Examiner withdraws the requirement for election of species; thus, claims 40-44 remain withdrawn from consideration for being drawn to non elected subject matter. Claims 1, 6-8, 24, 28, 30-32, 52 and 58-62 are currently examined.

Withdrawn claim rejections

- 2. The rejection of claims 1, 6-8, 24, 28, 30, 52 and 58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the amendments to the claims.
- 3. The rejection of claim 52 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in view of the amendments to the claim.
- 4. The rejection of claims 1, 24, 28, 3052 and 58 under 35 U.S.C. 102(b) as being anticipated by Pestka et al. is withdrawn in view of the amendments to the claims and the persuasive arguments of Applicant.

New claim rejections and objections necessitated by amendment

Claim Objections

5. Claim 61 is objected to because of the following informalities: the word "performed" should be inserted in line 1 after "is". Appropriate correction is required.

Claim interpretation

6. The claim 32 is interpreted as drawn to an isolated nucleic acid comprising a sequence as defined in SEQ ID NO: 1 or a fragment thereof wherein the fragment comprises SEQ ID NO: 3.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1647

8. Claims 1, 6-8, 32 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (U.S. Pat. No. 7,407,744- filed 07/23/2004).

Liu et al. teach 45 viral ORFs essential for viral replication and characterized 115 growth-dispensable viral genes of the human CMV (col. 2, lines18-24). Sequences of the gene are used in the development of vectors. Protein products of the genes are useful as targets for drug design, as targets for immunological agents, and the like. The mutant HCMV are useful in a number of screening methods. Screening methods include the growth of HCMV in different human cell lines (Col. 2, lines 45-62). The SEQ ID NO: 1 of the Liu et al. comprises fragments of SEQ ID NO: 1 of the instant Application (and also SEQ ID NO: 3 of the instant Application) and thus it is considered that anticipates the claims 1, 6-8, 32 and 58 of the instant Application.

```
RESULT 1
US-10-897-508-1
; Sequence 1, Application US/10897508
; Patent No. 7407744
; GENERAL INFORMATION:
  APPLICANT: Fenyong Liu
  APPLICANT: Walter Dunn
; APPLICANT: CASSIE CHOU
  TITLE OF INVENTION: CYTOMEGALOVIRUS GENE FUNCTION AND
  TITLE OF INVENTION: METHODS FOR DEVELOPING ANTIVIRALS, ANTI-CMV VACCINES,
AND
  TITLE OF INVENTION: CMV-BASED VECTORS
  FILE REFERENCE: BERK-025
  CURRENT APPLICATION NUMBER: US/10/897,508
; CURRENT FILING DATE: 2004-07-23
; PRIOR APPLICATION NUMBER: 60/490,200
; PRIOR FILING DATE: 2003-07-25
 NUMBER OF SEQ ID NOS: 1
  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 1
   LENGTH: 218802
   TYPE: DNA
   ORGANISM: cytomegalovirus
   FEATURE:
  NAME/KEY: misc feature
   LOCATION: 19769
   OTHER INFORMATION: n = A, T, C or G
```

Art Unit: 1647

```
US-10-897-508-1
                  87.8%;
                        Score 654.6; DB 7;
                                       Length 218802;
 Query Match
 Best Local Similarity 90.3%;
 Matches 741; Conservative
                       2; Mismatches
                                    2;
                                              76;
                                       Indels
                                                 Gaps
1;
     1 CATAAAGGACCACCTACCTGGGACGCGCAGTTGGGCGGGGACTGGGACGGCATGCTGCG 60
Qy
       Db 149288 CATAAAGGACCACCTACCTGGGACGCGCAGTTGGGCGGCGGACTGGGGCGGCATGCTGCG 149347
     61 GTGATGCTGTCGGTGATGGTCTCTTCCTCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCT 120
Qу
       Db 149348 GTGATGCTGTCGGTGATGGTCTCTTCCTCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCT 149407
    121 TCCGAGGAGGCGAAGCCGGCGACGACGACGACGATAAAGAATACAAAGCCGCAGTGTCGT 180
QУ
       Db 149408 TCCGAGGAGGCGAAGCCGGCGACGACGACGATAAAGAATACAAAGCCGCAGTGTCGT 149467
    181 CCAGAGGATTACGCGACCAGATTGCAAGATCTCCGCGTCACCTTTCATCGAGTAAAACCT 240
QУ
       Db 149468 CCAGAGGATTACGCGACCAGATTGCAAGATCTCCGCGTCACCTTTCATCGAGTAAAACCT 149527
    241 ACGTT---
QУ
       11111
246 -----GCAACGTGAGGACGACTACTCCGTGTGGCTCGACGGTAC 284
QУ
                      Db 149588 TGACGTAGTTTTCCTCTTGTAGCAACGTGAGGACGACTACTCCGTGTGGCTCGACGGTAC 149647
    285 GGTGGTCAAAGGCTGTTGGGGATGCAGCGTCATGGACTGGTTGTTGAGGCGGTATCTGGA 344
QУ
       Db 149648 GGTGGTCAAAGGCTGTTGGGGATGCAGCGTCATGGACTGGTTGTTGAGGCGGTATCTGGA 149707
    345 GATCGTGTTCCCCGCAGGCGACCACGTCTATCCCGGACTCAAGACGGAATTGCATAGTAT 404
QУ
       Db 149708 GATCGTGTTCCCCGCAGGCGACCACGTCTATCCCGGACTCAAGACGGAATTGCATAGTAT 149767
    405 GCGCTCGACGCTAGAATCCATCTACAAAGACATGCGGCAATGCGTAAGTGTCTCTGTGGC 464
Qy
       Db 149768 GCGCTCGACGCTAGAATCCATCTACAAAGACATGCGGCAATGCGTAAGTGTCTCTGTGGC 149827
    465 GGCGCTGTCCGCACAGAGGTAACAACGTGTTCATAGCACGCTGTTTTACTTTTGTCGGGC 524
QУ
       Db 149828 GGCGCTGTCCGCGCAGAGGTAACAACGTGTTCATAGCACGCTGTTTTACTTTTGTCGGGC 149887
    525 TCCCAGCCTCTGTTAGGTTGCGGAGATAAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCG 584
QУ
       Db 149888 TCCCAGCCTCTGTTAGGTTGCGGAGATAAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCG 149947
    585 GAAAGGAAATCGGATAACGGCACGCGGAAAGGTCTCAGCGAGTTGGACACGTTGTTTAGC 644
Qу
       Db 149948 GAAAGGAAATCGGATAACGGCACGCGGAAAGGTCTCAGCGAGTTGGACACGTTGTTTAGC 150007
```

Art Unit: 1647

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.

Art Unit: 1647

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 12. Claims 24, 28, 30-31, 52 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (U.S. Pat. No. 7,407,744- filed 07/23/2004) in view of Williams et al. (U.S. Pat. No. 7,361,460- filed 04/11/2003).

The claims are drawn to a method for screening a subject for infection by a virus of the herpesvirideae group, the method comprising: (a) obtaining a biological sample from said subject; (b) contacting said biological sample from said subject with an isolated nucleic acid sequence of claim 1; and (c) detecting the presence or absence of hybridization between a nucleic acid in said biological sample and the isolated nucleic acid of claim 1, wherein the presence of hybridization indicates infection. Further limitations are added to the isolated nucleic acid used in terms of length. The detection method may also be PCR based using primers from the C-terminus of the SEQ ID NO:1. Also claimed is a kit comprising an isolated nucleic acid and reagents for hybridization.

The teachings of Liu et al. were presented supra. Even though they envision the use of the nucleic acid as screening tools, they are silent about the actual methodology or about a kit that uses them.

Williams et al. teach accurate, sensitive, and efficient methods for molecular diagnosis of human papillomavirus (HPV)-based disease, where the method improves the accuracy and reliability of diagnostic and prognostic assessments of HPV-based disease (abstract). One of the methods for the diagnosis of HPV infection comprises a

primary screen for detecting HPV nucleic acids by hybridization with DNA or RNA probes directed against specific types of HPV. Several different HPV hybridization methodologies may be used including, but not limited to, Southern blot, Dot blot, Slot blot, and in situ hybridization. Other non-limiting examples of techniques for detecting HPV nucleic acids include, polymerase chain reaction (PCR) including both low stringency (broadly cross-reactive) and high stringency (type-specific) methods. PCR-based methods have been used successfully for the detection and typing of genital HPV genotypes in clinical specimens, such as cervical swabs or scrapes, saline cervicovaginal lavages, frozen biopsies, and formalin-fixed paraffin-embedded tissues (col.6, lines 8-35). Also taught are kits for diagnosing the HPV-based disease (col. 4, lines 17-19).

Page 8

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used the fragments of Liu et al. (which comprise SEQ ID NO: 3 of the instant Application) to diagnose a viral infections by the procedures described by Williams et al. with a reasonable expectation of success. This is because Liu et al. suggested the use of the fragments and Williams et al. is just an example of an application of known techniques to diagnose diseases based on nucleic acid detection and possible using the reagents in a kit. A person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ELLY-GERALD STOICA whose telephone number is

(571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-

18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elly-Gerald Stoica/ Examiner, Art Unit 1647